

Attorney Docket No. 2481,1767  
Application No.: 10/014,472

**REMARKS**

Reconsideration and reexamination of this application are respectfully requested.

In the Advisory Action the Office stated that "Yeda discloses the administration of low molecular weight heparin (enoxaparin) compositions for the prevention and/or treatment of pathological processes involving the induction of TNF- $\alpha$  secretion." The Office further alleged that osteoarthroses, which is recited in claim 3, "is an example of a degenerative joint disorder according to page 4 of the instant disclosure and [is] thus anticipated by Yeda." Applicants respectfully traverse.

According to Yeda, "The disorders that can be prevented or treated according to the invention are all disorders linked in pathological processes involving induction of TNF- $\alpha$  secretion, including atherosclerosis and vasculities and pathological processes related thereto; autoimmune diseases, e.g., rheumatoid arthritis, diabetes type I (IDDM) . . . ." (Yeda at page 12, lines 30-36.) Yeda does not disclose use of enoxaparin to treat osteoarthroses, or to treat any disorder that is not linked to pathological process involving induction of TNF- $\alpha$  secretion.

It appears to Applicants that the Office may be assuming that TNF- $\alpha$  secretion is a cause of osteoarthroses. However, while TNF- $\alpha$  secretion is a cause of rheumatoid arthritis, it is not involved in causing osteoarthroses. For example, an article published on the web site of the Arthritis Research Campaign of the United Kingdom in 2004, entitled "Anti-TNF Therapy (Etanercept, Infliximab and Adalimumab) for Rheumatoid Arthritis," indicates that drugs that target TNF are used to treat rheumatoid arthritis. (Exhibit A.) However, the article goes on to state that "Osteoarthritis and rheumatoid arthritis are two completely different disease processes, and while anti-TNF may help to

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alleviate the inflammation of rheumatoid arthritis, it has no effect on degenerative conditions such as osteoarthritis." (Exhibit A at page 2.) The non-involvement of TNF- $\alpha$  secretion in osteoarthritis is further demonstrated in an abstract published in 2002 by Nevitt et al., entitled "Inflammation Markers (CRP, TNF- $\alpha$ , IL-6) are not Associated With Radiographic or MRI Findings of Knee OA in the Elderly: The Health ABC Study." (Exhibit B.) According to Nevitt et al., no increase in TNF- $\alpha$  secretion is observed in patients with knee osteoarthritis versus control patients. (Exhibit B.) Thus, as reflected in Exhibits A and B, osteoarthritis is not a disorder linked to a pathological process involving induction of TNF- $\alpha$ .

Yeda does not disclose a method of treating any of the disorders recited in Applicants' claims. Thus, Yeda does not anticipate any of Applicants' claims. See *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); M.P.E.P. § 2131. Accordingly, Applicants respectfully request that the Office withdraw the anticipation rejection of the pending claims over Yeda.

In the Advisory Action the Office also indicated that the Amendment filed November 3, 2004, raises new issues under 35 U.S.C. § 112, second paragraph, relating to an alleged lack of antecedent basis for a term or terms appearing in the amended claims. Applicants have reviewed the pending claims and respectfully submit that the claims comply with all requirements of 35 U.S.C. § 112, second paragraph. In the event that the Office disagrees, Applicants urge the Examiner to contact the undersigned to resolve this issue.

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In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims 1, 3-8, and 26-30.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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